

Underutilization of a validated treatment satisfaction instrument in inflammatory bowel disease

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Background

- Patient satisfaction with treatment is an increasingly recognized element of value.¹
- Medication satisfaction is of particular importance for patients with chronic conditions, such as Crohn's disease (CD) and ulcerative colitis (UC), who require long-term treatment.²⁻⁴
- Low treatment satisfaction has been suggested as a predictor of poor adherence, which is associated with negative clinical outcomes.³⁻⁶
- The Treatment Satisfaction Questionnaire for Medication (TSQM) is a validated instrument measuring patient satisfaction with medication that may predict adherence.⁶

Objective

- We aimed to explore the employment of the TSQM in clinical trials in inflammatory bowel disease (IBD).
- We further examined the inclusion of TSQM results in subsequent publications.

Conclusions

- TSQM is a patient-reported outcome measure that reports on perceived effectiveness and may be linked to treatment adherence in IBD.
- Despite its potential value, only a small fraction of identified studies employed TSQM and only two examined adherence simultaneously.
- A validated measure providing information about a key value driver may be underutilized in clinical studies and publications, representing an opportunity to differentiate in a crowded treatment landscape.

Methods

Clinicaltrials.gov search

- We conducted a search of clinicaltrials.gov on September 9, 2022.
- Separate searches were performed using "Crohn's Disease" and "Ulcerative Colitis" as the condition or disease term. Each disease search was re-run with TSQM as an additional search term.
- Included trials were recruiting, not yet recruiting, active but not recruiting, completed, or enrolling by invitation. Withdrawn, suspended, terminated, or unknown status trials were excluded.
- No other limits including country specifications were applied.

Literature review

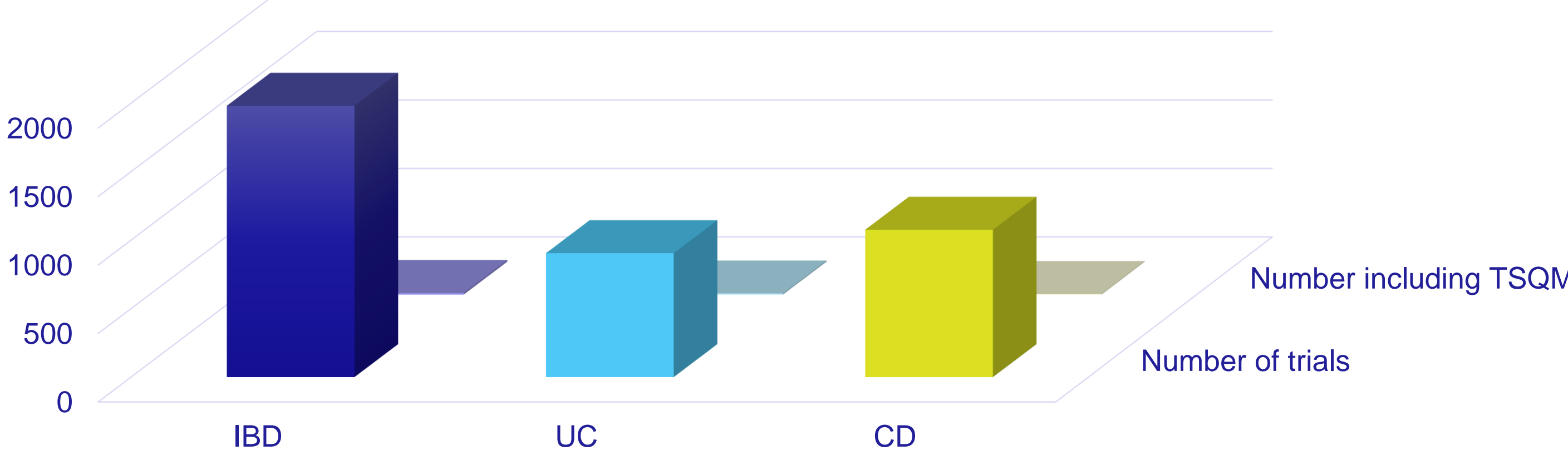
- An additional set of PubMed searches were conducted using the index terms "ulcerative colitis", "Crohn's disease", "inflammatory bowel disease", and TSQM.
- No year or language limits were applied.
- Identified records were title abstract screened for inclusion by a single reviewer and key information was extracted.
- Clinical trials were matched to those identified via the clinicaltrials.gov search.

Results

- Of a total of 1981 IBD trial records identified (905 UC and 1076 CD), only 12 employed the TSQM (8 UC, 4 CD) according to clinicaltrials.gov listings (**Figure 1**).
- In UC, 7 studies were observational; the single interventional study was a phase 3 study of adalimumab.
- The most common outcome was mean change from baseline in TSQM score, while 2 studies specified TSQM items (modalities, satisfaction, effectiveness, side effects).
- For CD, all 4 studies were observational. Identified studies were completed with the exception of 2, a long-term registry and a study of ozanimod in UC.

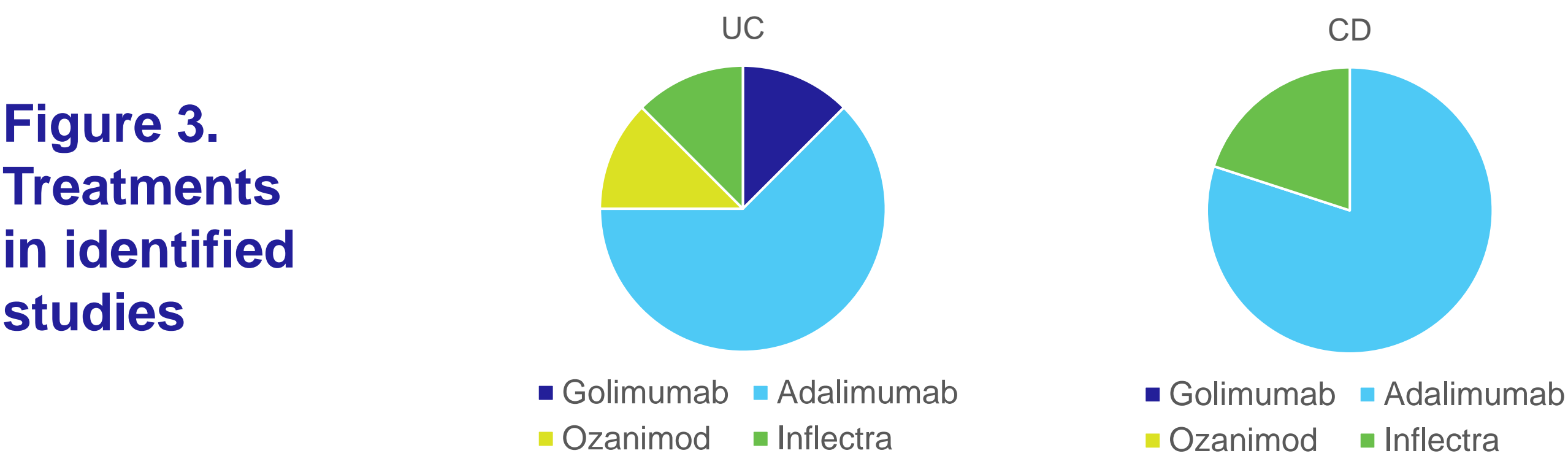
- All of the studies had a single intervention, which was most commonly adalimumab (**Figure 3**). For several approved IBD therapies, no studies with TSQM were identified. No studies of non-FDA/EMA approved therapies were identified.
- The most common outcomes measured in identified trials with TSQM were Short Inflammatory Bowel Disease Questionnaire (SIBQ), healthcare resource utilization (HCRU), work productivity and activity impairment (WPAI), and safety (**Figure 4**).
- Overall, 2 studies also employed measures of adherence: Morisky Medication Adherence Scale and percentage of patients with medication possession ratio ≥80%. These studies included patients with both UC and CD.

Figure 1. Number of studies including TSQM



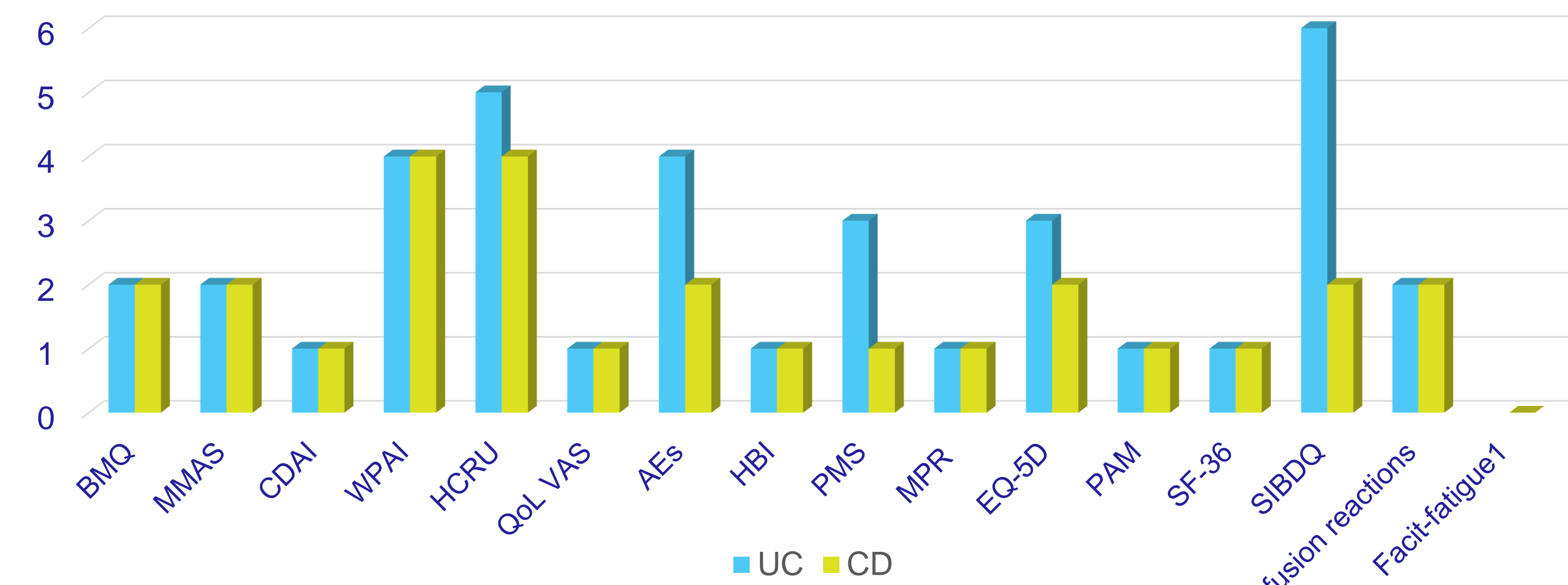
Abbreviations: CD, Crohn's disease; IBD, inflammatory bowel disease; TSQM, Treatment Satisfaction Questionnaire for Medication; UC, ulcerative colitis

Figure 3. Treatments in identified studies



Abbreviations: CD, Crohn's disease; UC, ulcerative colitis

Figure 4. Other included measures in studies including TSQM



Abbreviations: AEs, adverse events; BMQ, Beliefs About Medication Questionnaire; CD, Crohn's disease; CDAl, Clinical Disease Activity Index; EQ-5D, EuroQol 5 dimension; HBI, Harvey Bradshaw Index; HCRU, healthcare resource utilization; MMAS, Morisky Medication Adherence Scale; MPR, Medication Possession Ratio; PAM, Patient Activation Measure; PMS, Partial Mayo Score; QoL VAS, Quality of life visual analog scale; SF-36, Short-Form 36; SIBDQ, short inflammatory bowel disease questionnaire; UC, ulcerative colitis; WPAI, Work Productivity and Activity Impairment Questionnaire

Subsequent publications

- Among the identified records on clinicaltrials.gov, only 4 resulting publications were identified:
 - 1 multicenter, cross-sectional adalimumab dose-escalation study⁷
 - 1 real-world, observational study of golimumab in UC⁸
 - 1 cross-sectional, retrospective preference study in UC⁹
 - 1 validation of another satisfaction instrument in CD¹⁰

Limitations

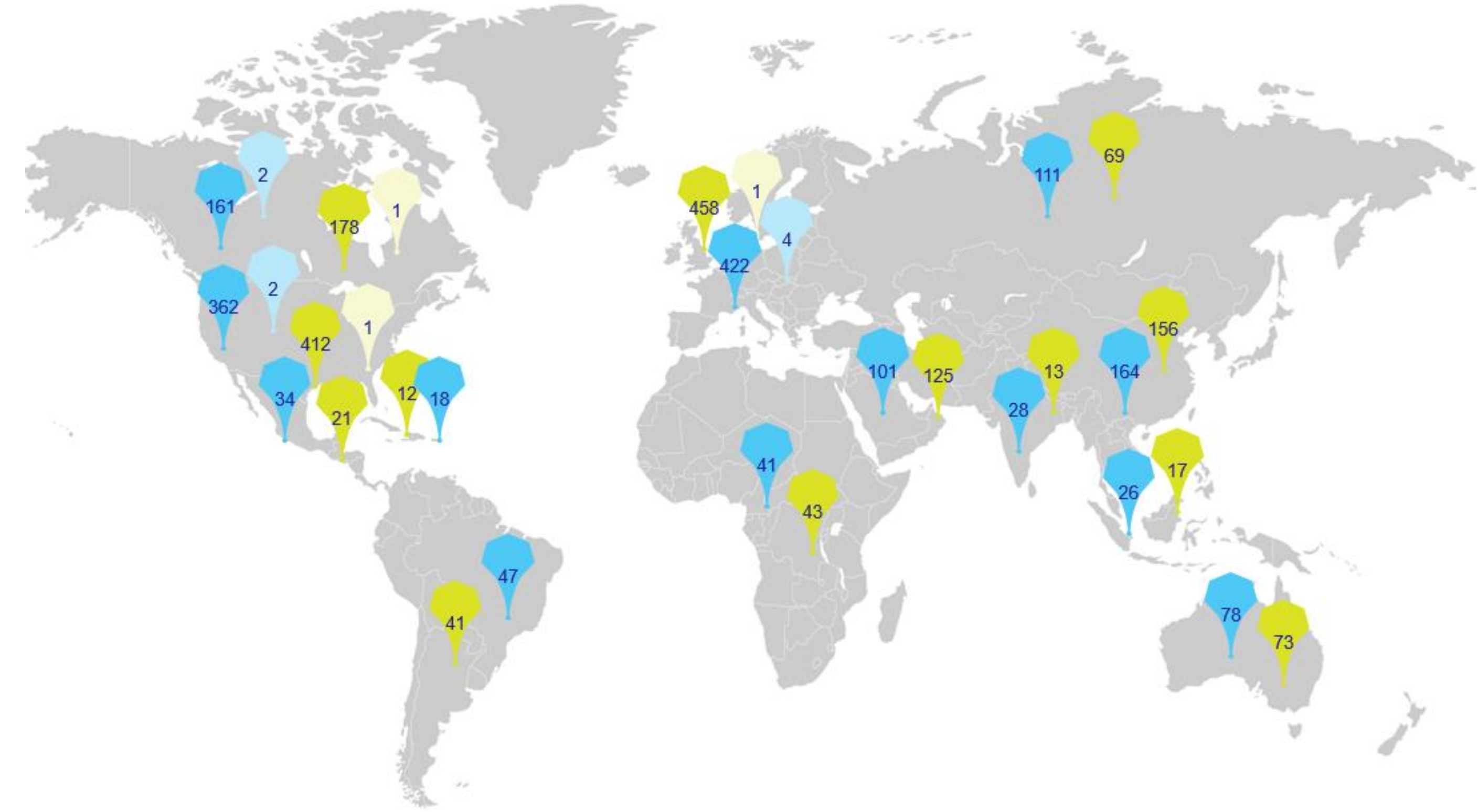
- There are several limitations to this research that should be acknowledged. Of note, clinicaltrials.gov listings do not always contain the final trial protocols or all exploratory endpoints. As such, employment of the TSQM may be underestimated.
- This was a focused review and not a systematic literature review. While our approach used broad search terms for inclusiveness, heterogeneity in reporting may have resulted in missed identification of relevant publications. We also would not have captured abstracts that were not yet indexed on PubMed.
- Future work should include a comprehensive evaluation of how TSQM and adherence information is used in value assessments.

Disclosures

- None.

- The only studies that included TSQM were in the US, Europe, and Canada. Clinical trials in Asia-Pacific and emerging markets did report TSQM as an endpoint (**Figure 2**).

Figure 2. Geographic overview of included studies



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Abbreviations: CD, Crohn's disease; IBD, inflammatory bowel disease; HCRU, healthcare resource utilization; SIBDQ, Short Inflammatory Bowel Disease Questionnaire; TSQM, Treatment Satisfaction Questionnaire for Medication; UC, ulcerative colitis; WPAI, work productivity and activity impairment.